



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/529,608

03/30/2005

Martin Alan Lee

41577/314229

1746

23370 7590 12/23/2008

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,608	Applicant(s) LEE ET AL.	
	Examiner Jan M. Ludlow	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/2005, 8/18/2008</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1797

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1797

5. Claims 1-4, 8-10, 13, 14, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Christie (GB 2355792).

Christie teaches an apparatus made of pliable plastic having a first chamber 101 with sealing means 107, a second chamber 102 with sealing means 108 and a duct 104 leading from the base of the first chamber externally to the top of second chamber. The first chamber 101 may have a volume of 500 ml (p. 21, line 9). In use, sample is provided in the first chamber and pretreated with a functional reagent such as an anti-foam agent. Additional reagents may be organic or inorganic or biological (p. 5, lines 26-28), and the analysis procedure is applicable to a wide variety of species (p. 2, lines 1-2). The bottle is then squeezed to fill the second chamber to fill level 104b and the excess drained back into the first chamber (pages 21-23). The sample may be fermentation broth (p. 17, lines 1-6), which inherently includes nucleic acid, as from yeast. With respect to claim 8, it is the examiner's position based on the construction of the device that at least 10% accuracy is inherent. With respect to claim 9, the first chamber is structurally capable of receiving a funnel. With respect to claim 13, inverted conical seal 202, 204 is provided for the second chamber and a functional reagent, such as the enzyme in the enzyme electrode 305, is provided.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christie.

Christie fails to teach the claimed volumes.

It would have been obvious to size the second chamber and duct in proportion to the first chamber as shown and/or in order to isolate a desired volume of fluid.

Art Unit: 1797

7. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (4562043).

Mennen teaches a device having a first chamber 21, a sealing means 24 containing a pre-determined volume of solvent, duct 29 and second chamber 16. A solid sample is applied to surface 22 and inserted into the second chamber. The solvent is placed in the first chamber by breaking the sealing means, and the solvent is pumped into the second chamber by gravity and the inherent capillarity of pledget 31. Occult blood is dissolved from the solid sample and carried into the pledget for reaction. See, e.g., Figures 1-5, col. 8.

8. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christie (GB 2355792) in view of Petersen (6818185).

Christie teaches an apparatus made of pliable plastic having a second chamber 101 with sealing means 107, a first chamber 102 with sealing means 108 covering an opening, and a duct 104 leading from the base of the first chamber externally to the top of second chamber. In use, sample is provided in the second chamber and pretreated with a functional reagent such as organic or inorganic or biological reagents (p. 5, lines 26-28), and the analysis procedure is applicable to a wide variety of species (p. 2, lines 1-2).

Christie fails to teach the claimed reagents.

Petersen teaches a container for treating cell samples. Beads for lysing cells (col. 10, lines 1-2), an oligonucleotide sequence for binding DNA or RNA from lysed

Art Unit: 1797

cells (col. 10, lines 7-9), and chaotropic salts for lysing cells may be provided (col. 18, line 45).

It would have been obvious to provide lysing beads, specified nucleic acid sequences and chaotropic salts in the device of Christie in order to process cell samples as taught by Petersen.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nason additionally teaches pumping fluid from first chamber 14 to dissolve sample from swab 24 in second chamber 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jan M. Ludlow
Primary Examiner
Art Unit 1797

/Jan M. Ludlow/
Primary Examiner, Art Unit 1797